

**IN THE DISTRICT COURT IN AND FOR POLK COUNTY**

THE STATE OF IOWA, ex. rel.	)	<b>PETITION</b>
THOMAS J. MILLER, ATTORNEY GENERAL	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Case No. EQCE080908
Bristol-Myers Squibb Company	)	
	)	
Defendant.	)	

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**Introduction**

Plaintiff, the State of Iowa ex. rel. Attorney General Thomas J. Miller, by Assistant Attorney General Amy Licht, brings this action complaining of Defendant Bristol-Myers Squibb Company for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

**The Parties**

1. Plaintiff is the State of Iowa ex. rel. Attorney General Thomas J. Miller.
2. The Attorney General is charged, inter alia, with enforcement of the Consumer Fraud Act, Iowa Code section 714.16 (“Consumer Fraud Act” or “CFA”).
3. Defendant Bristol-Myers Squibb Company, (“Defendant” and/or “BMS”), is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York 10154.
4. At all relevant times hereto, Defendant BMS transacted business in the State of Iowa and nationwide by advertising, soliciting, selling, promoting, marketing and distributing prescription drugs, including the atypical antipsychotic prescription drug Abilify, and that business is governed by the CFA.

**Jurisdiction and Venue**

5. This Court has jurisdiction over the Defendant pursuant to Iowa Code section 714.16 because the Defendant has transacted business within the State of Iowa at all times relevant to this petition.

6. Venue is proper in Polk County pursuant to Iowa Code section 714.16(10) because Defendant BMS has transacted business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

**Background**

7. Abilify is one of several second-generation antipsychotic prescription drugs, commonly referred to as “atypical antipsychotics,” that were originally used to treat schizophrenia. Most or all of these drugs have since been approved for a number of mental disorders.

8. Atypical antipsychotics can produce dangerous side effects, including cerebrovascular complications, movement disorders, diabetes, hyperglycemia, weight gain, and other severe conditions.

9. Abilify, the brand name for the prescription drug aripiprazole, was first approved by the Food and Drug Administration (“FDA”) for the treatment of schizophrenia in adults only in November 2002. Since then, the FDA has approved various formulations of Abilify for several indications, including: for the acute treatment of manic and mixed episodes in Bipolar I Disorder in adults and in pediatric patients aged 10-17, for the treatment of schizophrenia in adolescent patients 13 to 17 years of age, for adjunctive treatment of major depressive disorder, in adults, for the treatment of irritability associated with autistic disorder in pediatric patients

aged 6 to 17 years, and for the treatment of Tourette's disorder in pediatric patients aged 6 to 18 years.

**Defendant's Course of Conduct**

10. BMS began to market Abilify to health care professionals not only for the treatment of schizophrenia in adults in 2002, but also for a number of uses for which it was not approved by the FDA. The promotion of a drug for uses for which it is not approved by the FDA is known as off-label marketing. For example, BMS promoted Abilify off-label for use in children. BMS also promoted Abilify for use in elderly patients with symptoms consistent with dementia and Alzheimer's disease without first establishing the drug's safety and efficacy for those uses and despite the lack of FDA approval for these uses. In fact, in 2006, Abilify received a "black box" warning that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death.

11. BMS implicitly misrepresented Abilify's approved uses when BMS promoted and marketed Abilify for uses for which it was not approved.

12. BMS also made material omissions when, among other matters, it failed to disclose the fact that Abilify was not approved for the uses for which it was promoted and marketed.

13. BMS made unsubstantiated claims about Abilify by minimizing and misrepresenting risks of the drug, such as metabolic and weight gain side effects, thereby making false and/or misleading representations about Abilify's risks.

14. BMS overstated the findings of scientific studies, for example, by using results of a randomized controlled trial to demonstrate long term efficacy of Abilify for stabilization and

maintenance in bipolar disorder, without disclosing in BMS's marketing messages to doctors the limitations of the study.

**Applicable Statutes**

15. Iowa Code section 714.16(2)(a) states in relevant part as follows:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

16. As used in the Consumer Fraud Act, the term "person" includes:

any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.

17. Neither all nor any part of the application for injunctive relief has previously been presented to or refused by any court or justice. Iowa R. Civ. P. 1.1504.

18. In an action by the State, no security shall be required of the State. Iowa R. Civ. P. 1.207.

**Violations of the Iowa Consumer Fraud Act**

19. The allegations contained in paragraphs 1-18 are incorporated by reference as if they were set out at length herein.

20. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore has engaged in practices that are unlawful under

Iowa Code section 714.16(2)(a), by misrepresenting the drug's approved uses, which had the capacity or tendency to deceive or mislead health care providers and patients.

21. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore has engaged in practices that are unlawful under Iowa Code section 714.16(2)(a), by making material omissions concerning the drug's approved uses that deceived or tended to deceive consumers.

22. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore has engaged in practices that are unlawful under Iowa Code section 714.16(2)(a), by representing that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have.

23. The Defendant, in the course of minimizing and misrepresenting risks, engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore has engaged in practices that are unlawful under Iowa Code section 714.16(2)(a), by making false, misleading, or other representations about Abilify's side effects that had the capacity, tendency, or effect of deceiving or misleading consumers.

24. The Defendant, in the course of overstating the findings of scientific studies in marketing messages, engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore has engaged in practices that are unlawful under Iowa Code section 714.16(2)(a), by making false, misleading and other representations about scientific studies that had the capacity or tendency to deceive or mislead health care providers and patients.

**Remedies**

25. Iowa Code section 714.16(7), in relevant part, provides:

If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section....

....In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. In addition, on the motion of the attorney general or its own motion, the court may impose a civil penalty of not more than five thousand dollars for each day of intentional violation of a temporary restraining order, preliminary injunction, or permanent injunction issued under the authority of this section. A penalty imposed pursuant to this subsection is in addition to any penalty imposed pursuant to section 537.6113. Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund for the state.

26. Iowa Code section 714.16(11) provides:

In an action brought under this section, the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.

**Request for Relief**

WHEREFORE, the Plaintiff requests that this Court enter an Order:

- A. Issuing a permanent injunction prohibiting Defendant, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair, deceptive or misleading conduct, as provided by Iowa Code section 714.16(7);
- B. Ordering the Defendant to pay all costs for the prosecution and investigation of this action, as provided by Iowa Code sections 714.16(11);
- C. Ordering the Defendant to pay civil penalties of \$40,000 for each and every violation of the Consumer Fraud Act, as provided by Iowa Code section 714.16(7); and
- D. Granting such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

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Attorney General of Iowa

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